IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, SHIONOGI SEIYAKU KABUSHIKI KAISHA, and THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. **WATSON LABORATORIES, INC. (NV) and EGIS PHARMACEUTICALS PLC,** Defendants.	Civil Action No.: 10-915-LPS **REDACTED VERSION D.I. 133**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., AstraZeneca AB, Shionogi Seiyaku Kabushiki Kaisha, and The Brigham and Women's Hospital, Inc., for their Complaint against Watson Laboratories, Inc. (NV) and EGIS Pharmaceuticals PLC, hereby state as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e) and § 271(b). This action relates to a New Drug Application ("NDA") filed by or for the benefit of, *inter alia,* Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") and Watson Laboratories, Inc. (NV), with the United States Food and Drug Administration ("FDA") for approval to market versions of AstraZeneca's highly successful CRESTOR® pharmaceutical products that are sold in the United States. This also is an action against EGIS Pharmaceuticals PLC for inducement of infringement.

Parties

2. Plaintiff AstraZeneca UK Limited ("AZ UK") is a corporation operating and existing under the laws of the United Kingdom, with its principal place of business at 2 Kingdom Street, London, W2 6BD, England.

3. Plaintiff IPR Pharmaceuticals, Inc. ("IPR") is a corporation operating and existing under the laws of Puerto Rico, with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

4. Plaintiff AstraZeneca AB is a corporation operating and existing under the laws of Sweden with its principal place of business at S-151 85 Södertälje, Sweden.

5. Plaintiff Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") is a corporation operating and existing under the laws of Japan, with its principal place of business at 1-8, Doshomachi 3- chome, Chuo-ku, Osaka 541-0045 Japan.

6. Plaintiff The Brigham and Women's Hospital, Inc. ("Brigham") is a not-for-profit corporation operating and existing under the laws of Massachusetts with its principal place of business at 75 Francis Street, Boston, MA 02115.

7. On information and belief, Defendant Watson Laboratories, Inc. (NV) ("Watson Labs (NV)") is a corporation operating under the name Watson Laboratories, Inc., and is operating and existing under the laws of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, CA 92880.

8. On information and belief, Watson Labs (NV) is a wholly-owned subsidiary of Watson Pharmaceuticals and has some officers and directors in common with Watson Pharmaceuticals.

9. On information and belief, Defendant EGIS Pharmaceuticals PLC ("EGIS") is a corporation operating and existing under the laws of Hungary, with its principal place of business at 1106 Budapest, Keresztúri út 30-38, Hungary.

Background

10. IPR is the holder of approved NDA No. 021366 for CRESTOR® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium.

11. CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. CRESTOR® is one of the most effective lipid-lowering statins available. Over 21 million patients have been prescribed CRESTOR®, and over 281 million prescriptions have been written worldwide for CRESTOR®. Rosuvastatin calcium is the active ingredient in CRESTOR®.

12. Plaintiffs AZ UK, IPR, and AstraZeneca AB (collectively, the "AstraZeneca Plaintiffs"), themselves and through other AstraZeneca entities, and Shionogi manufacture, market, promote, educate the public and physicians about, and conduct research and development on existing and new indications for CRESTOR® Tablets, and financially benefit from sales of CRESTOR® Tablets in the United States.

13. By letter dated September 28, 2010, an entity named Watson Laboratories, Inc. notified certain Plaintiffs that it had filed with the FDA NDA No. 202172 seeking FDA approval to market in the United States rosuvastatin zinc tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths ("Watson Rosuvastatin Tablets"), and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(b)(3).

14. The notice letter is on letterhead bearing at the top Watson Pharmaceutical's logo, and at the bottom the name and address Watson Laboratories, Inc., 360 Mount Kemble Avenue, Morristown, NJ 07960. It was signed by Joyce DelGaudio, with the title Executive Director,

Regulatory Affairs, Watson Laboratories, Inc. On information and belief, Ms. DelGaudio also holds the position Executive Director, Regulatory Affairs, Watson Pharmaceuticals, Inc. The letter referred those Plaintiffs to an in-house counsel, Matthew O. Brady, at "Watson, 311 Bonnie Circle, Corona, CA 92880." On information and belief, Mr. Brady holds the position Senior IP Counsel at Watson Pharmaceuticals, Inc.

15. On October 19 and 20, 2010, certain Plaintiffs asked Mr. Brady to identify which of the multiple subsidiaries of Watson Pharmaceuticals that are named Watson Laboratories, Inc. submitted NDA No. 202172 to the FDA. As of the time of filing the original Complaint in this civil action, none of the Plaintiffs had received that information.

16. On October 26, 2010, Plaintiffs AZ UK, IPR, and Shionogi filed the original Complaint in this civil action against Watson Pharmaceuticals, Watson Labs (NV), and certain other subsidiaries of Watson Pharmaceuticals.

17. On December 17, 2010, Watson Pharmaceuticals, Watson Labs (NV), and the other Watson Pharmaceuticals' subsidiaries that originally were defendants in this civil action, and Plaintiffs AZ UK, IPR, and Shionogi, entered into a Stipulation Regarding Dismissal ("the Stipulation"), which they filed with the Court (D.I. 11). In the Stipulation, Watson Labs (NV), among other things, represented and warranted that it is the owner and applicant of NDA No. 202172, which it submitted to the FDA, and agreed that it would not contest venue, service of process, subject matter jurisdiction, or this Court's exercise of personal jurisdiction over it in this civil action. Also in the Stipulation, Plaintiffs AZ UK, IPR, and Shionogi, among other things, agreed to voluntarily dismiss without prejudice the Watson entities other than Watson Labs (NV) from this civil action. In response to the parties' joint motion for entry of a consent order pursuant to the Stipulation (D.I. 13), on December 23, 2010, the Court entered a Consent Order

Pursuant to Fed. R. Civ. P. 41(a)(2) dismissing without prejudice the original civil action against Watson Pharmaceuticals and the other Watson Pharmaceuticals subsidiaries that originally were defendants, leaving Watson Labs (NV) as the remaining defendant party (D.I. 14).

18. On information and belief, Watson Labs (NV) filed with the FDA, in Rockville, Maryland, NDA No. 202172 under 21 U.S.C. § 355(b)(2) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale of the Watson Rosuvastatin Tablets in the United States. On information and belief, the Watson Rosuvastatin Tablets contain a zinc salt form of rosuvastatin and are versions of the AstraZeneca Plaintiffs' CRESTOR® Tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths. On information and belief, NDA No. 202172 relies upon safety and efficacy investigations of the AstraZeneca Plaintiffs' CRESTOR® Tablets.

19. On information and belief, [redacted] EGIS filed with the FDA, in Rockville, Maryland, [redacted] Drug Master File ("DMF") No. 23592 for the manufacture of [redacted] rosuvastatin active pharmaceutical ingredient ("API"). On information and belief, if the FDA approves Watson's NDA No. 202172, [redacted].

Jurisdiction and Venue

20. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. In the Stipulation, Watson Labs (NV) agreed not to contest subject matter jurisdiction in this civil action.

21. This Court has personal jurisdiction over Watson Labs (NV). In the Stipulation, Watson Labs (NV) agreed not to contest personal jurisdiction over it in this civil action.

22. On information and belief, Watson Labs (NV) and Watson Pharmaceuticals, both directly and through Watson Pharmaceuticals' other wholly-owned subsidiaries, are engaged in the development, marketing, sale, and distribution of generic and brand pharmaceutical products throughout the United States, including Delaware.

23. On information and belief, Watson Pharma, Inc. ("Watson Pharma") is a corporation operating and existing under the laws of Delaware, and also is a wholly-owned subsidiary of Watson Pharmaceuticals.

24. On information and belief, Watson Pharmaceuticals organizes its operations by operating segment, including the Global Generics segment. On information and belief, the Global Generics segment is responsible for preparing, developing, and submitting NDAs and Abbreviated New Drug Applications ("ANDA") for generic counterparts to brand pharmaceutical products. On information and belief, the Global Generics segment relies upon contributions from Watson Pharmaceuticals and its wholly-owned subsidiaries, including Watson Labs (NV), in preparing, developing, and submitting NDAs and ANDAs, and in developing, manufacturing, marketing, and selling generic drug products. On information and belief, the Global Generic segment's products for the United States, including Delaware, are manufactured by, *inter alia,* Watson Labs (NV) and marketed and sold by Watson Pharma.

25. On information and belief, Watson Pharmaceuticals and Watson Labs (NV) have regularly sold products in Delaware, and elsewhere in the United States, through Watson Pharma. On information and belief, they have regularly done or solicited business, or engaged in a persistent course of conduct, in Delaware.

26. Personal jurisdiction over Watson Labs (NV) is proper because of, *inter alia*, its regular marketing and sales activities in Delaware, including the substantial, continuous, and

systematic distribution and sales of generic drug products to residents of Delaware. It purposefully avails itself of the privilege of selling Watson Pharmaceuticals' Global Generic segment's generic products in Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware.

27. This Court has personal jurisdiction over EGIS, pursuant to Fed. R. Civ. P. 4(k)(2). On information and belief, EGIS is not subject to personal jurisdiction in any state's courts of general jurisdiction, and exercising personal jurisdiction over EGIS is consistent with the United States Constitution and laws.

28. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b). In the Stipulation, Watson Labs (NV) agreed not to contest venue in this civil action.

COUNT I

Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(e)(2) by Watson

29. Plaintiffs AZ UK, IPR, and Shionogi (collectively, "the '314 Patent Plaintiffs") incorporate by reference paragraphs 1-28 of this Second Amended Complaint as if fully set forth herein.

30. United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives," was duly and legally reissued by the United States Patent and Trademark Office on August 7, 2001. The '314 Patent Plaintiffs hold all substantial rights in the '314 patent and have the right to sue for infringement thereof. A true and correct copy of the '314 patent is attached as Exhibit A.

31. Shionogi owns the '314 patent by assignment from the inventors. AZ UK is Shionogi's exclusive licensee under the '314 patent, and IPR is AZ UK's exclusive sublicensee under the '314 patent.

32. On information and belief, Watson Labs (NV) submitted to the FDA NDA No. 202172 in order to obtain approval to market the Watson Rosuvastatin Tablets in the United States before the expiration of the '314 patent. On information and belief, Watson Labs (NV) submitted to the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification alleging that the claims of the '314 patent are not infringed by the manufacture, use, or sale of the Watson Rosuvastatin Tablets.

33. Under 35 U.S.C. § 27l(e)(2)(A), the submission by Watson Labs (NV) to the FDA of NDA No. 202172 to obtain approval for the commercial manufacture, use, or sale of the Watson Rosuvastatin Tablets before the expiration of the '314 patent constitutes infringement of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

34. On information and belief, if the FDA approves NDA No. 202172, Watson Labs (NV) intends to market, offer for sale, and sell the Watson Rosuvastatin Tablets in the United States before the expiration of the '314 patent through Watson Pharmaceuticals' Global Generic segment.

35. On information and belief, Watson Labs (NV) and Watson Pharmaceuticals have acted in concert, actively supporting, participating in, and encouraging the submission to the FDA of NDA No. 202172. On information and belief, they did so in preparation to market and sell in the United States, including Delaware, the Watson Rosuvastatin Tablets. On information and belief, they intend to market and sell the Watson Rosuvastatin Tablets in the United States before the expiration of the '314 patent and any additional periods of exclusivity, if the FDA approves NDA No. 202172 before then.

36. On information and belief, when NDA No. 202172 was submitted to the FDA, Watson Labs (NV) and Watson Pharmaceuticals had knowledge of the '314 patent, and

knowingly infringed the '314 patent. On information and belief, Watson Labs (NV) submitted NDA No. 202172 to the FDA despite an objectively high likelihood that Watson Labs (NV)'s actions constitute infringement of a valid patent, and this risk was either known to Watson Labs (NV) and Watson Pharmaceuticals, or so obvious that it should have been known to them.

37. On information and belief, Watson Labs (NV)'s and Watson Pharmaceuticals' refusal to identify the Watson Laboratories, Inc. entity that filed NDA No. 202172 with the FDA, which necessitated the filing of the original Complaint with civil actions against multiple defendants in this and various jurisdictions, reflects their intent and willful infringement.

38. The '314 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '314 Patent Plaintiffs have no adequate remedy at law.

COUNT II

Infringement of United States Patent No. 6,858,618 Under 35 U.S.C. § 271(e)(2) by Watson

39. Plaintiffs AstraZeneca AB and AZ UK (collectively, "the '618 Patent Plaintiffs") incorporate by reference paragraphs 1-38 of this Second Amended Complaint as if fully set forth herein.

40. United States Patent No. 6,858,618 B2 ("the '618 patent"), entitled "Use of Rosuvastatin (ZD-4522) in the Treatment of Heterozygous Familial Hypercholesterolemia," was duly and legally issued by the United States Patent and Trademark Office on February 22, 2005. The '618 Patent Plaintiffs hold all substantial rights in the '618 patent and have the right to sue for infringement thereof. A true and correct copy of the '618 patent is attached as Exhibit B.

41. As of August 1, 2007, IPR had listed the '618 patent with the FDA for publication in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1) and the FDA had published that listing on the FDA's Internet website.

42. On information and belief, Watson Labs (NV) submitted to the FDA NDA No. 202172 in order to obtain approval to market the Watson Rosuvastatin Tablets in the United States before the expiration of the '618 patent.

43. On information and belief, if the FDA approves NDA No. 202172, Watson Labs (NV) intends to market, offer for sale, and sell the Watson Rosuvastatin Tablets in the United States before the expiration of the '618 patent through Watson Pharmaceuticals' Global Generic segment.

44. On October 15, 2009, the FDA approved adding to the CRESTOR® label a separate indication for the use of CRESTOR® to treat pediatric patients 10 to 17 years of age having Heterozygous Familial Hypercholesterolemia ("HeFH"), and adding to the label additional material information supporting the use, safety, and efficacy of the drug for that use by prescribers and their patients. A copy of that amended label is attached as Exhibit C.

45. On information and belief, the label for the Watson Rosuvastatin Tablets will include information relating to the use to treat patients having HeFH. A copy of the label that Watson Labs (NV) proposed for the Watson Rosuvastatin Tablets is attached as Exhibit D (filed under seal).

46. On information and belief, the labeling associated with the Watson Rosuvastatin Tablets causes NDA No. 202172 to be an application for a drug the use of which is claimed in the '618 patent in violation of 35 U.S.C. § 271(e)(2)(A).

47. On information and belief, if the FDA approves NDA No. 202172, the sale of the Watson Rosuvastatin Tablets in the United States with their associated labeling before the expiration of the '618 patent will cause infringement of one or more claims of the '618 patent.

48. On information and belief, the Watson Rosuvastatin Tablets, if approved by the FDA, will be prescribed and administered to human patients to treat HeFH, which uses will constitute direct infringement of the '618 patent. On information and belief, these uses will occur with Watson Lab (NV)'s specific intent and encouragement, and will be uses that Watson Labs (NV) knows or should know will occur. On information and belief, Watson Labs (NV) will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of the '618 Patent Plaintiffs' rights under the '618 patent.

49. Under 35 U.S.C. § 271(e)(2)(A), the submission by Watson Labs (NV) to the FDA of NDA No. 202172 to obtain approval for the commercial manufacture, use, or sale of the Watson Rosuvastatin Tablets before the expiration date of the '618 patent, which claims a use of those Tablets, constitutes infringement of one or more claims of the '618 patent, either literally or under the doctrine of equivalents.

50. Watson Labs (NV) was required to file a Paragraph IV certification regarding the '618 Patent pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), but failed to do so.

51. The '618 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '618 Patent Plaintiffs have no adequate remedy at law.

COUNT III

Infringement of United States Patent No. 7,030,152 Under 35 U.S.C. § 271(e)(2) by Watson

52. Plaintiffs IPR and Brigham (collectively, "the '152 Patent Plaintiffs") incorporate by reference paragraphs 1-51 of this Second Amended Complaint as if fully set forth herein.

53. United States Patent No. 7,030,152 B1 ("the '152 patent"), entitled "Systematic Inflammatory Markers as Diagnostic Tools in the Prevention of Atherosclerotic Diseases and as Tools to Aid in the Selection of Agents To Be Used for the Prevention and Treatment of Atherosclerotic Disease," was duly and legally issued by the United States Patent and Trademark Office on April 18, 2006, and was assigned to Brigham. The '152 Patent Plaintiffs hold all substantial rights in the '152 patent and have the right to sue for infringement thereof. A true and correct copy of the '152 patent is attached as Exhibit E.

54. As of March 8, 2010, IPR had listed the '152 patent with the FDA for publication in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1) and the FDA thereafter published that listing on the FDA's Internet website.

55. On information and belief, Watson Labs (NV) filed NDA No. 202172 in order to obtain approval to market the Watson Rosuvastatin Tablets in the United States before the expiration of the '152 patent.

56. On information and belief, if the FDA approves NDA No. 202172, Watson Labs (NV) intends to market, offer for sale, and sell the Watson Rosuvastatin Tablets in the United States before the expiration of the '152 patent through Watson Pharmaceuticals' Global Generic segment.

57. On February 8, 2010, the FDA approved adding to the CRESTOR® label a separate indication for the use of CRESTOR® for the primary prevention of cardiovascular

disease and adding to the label additional material information supporting the use, safety, and efficacy of the drug for that use by prescribers and their patients. A copy of that amended label is attached as Exhibit C.

58. On information and belief, the label for the Watson Rosuvastatin Tablets will include information relating to the use for the primary prevention of cardiovascular disease. A copy of the label that Watson Labs (NV) proposed for the Watson Rosuvastatin Tablets is attached as Exhibit D (filed under seal).

59. On information and belief, the labeling associated with the Watson Rosuvastatin Tablets causes NDA No. 202172 to be an application for a drug the use of which is claimed in the '152 patent in violation of 35 U.S.C. § 271(e)(2)(A).

60. On information and belief, if the FDA approves NDA No. 202172, the sale of the Watson Rosuvastatin Tablets in the United States with their associated labeling before the expiration of the '152 patent will cause infringement of one or more claims of the '152 patent.

61. On information and belief, the Watson Rosuvastatin Tablets, if approved by the FDA, will be prescribed and administered to human patients for the primary prevention of cardiovascular disease, which uses will constitute direct infringement of the '152 patent. On information and belief, these uses will occur with Watson Lab (NV)'s specific intent and encouragement, and will be uses that Watson Labs (NV) knows or should know will occur. On information and belief, Watson Labs (NV) will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of the '152 Patent Plaintiffs' rights under the '152 patent.

62. Under 35 U.S.C. § 271(e)(2)(A), the submission by Watson Labs (NV) to the FDA of NDA No. 202172 to obtain approval for the commercial manufacture, use, or sale of the

Watson Rosuvastatin Tablets before the expiration date of the '152 patent, which claims a use of those Tablets, constitutes infringement of one or more claims of the '152 patent, either literally or under the doctrine of equivalents.

63. Watson (NV) was required to file a Paragraph IV certification regarding the '152 patent pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), but failed to do so.

64. The '152 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '152 Patent Plaintiffs have no adequate remedy at law.

COUNT IV

Inducement of Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(b) by EGIS

65. The '314 Patent Plaintiffs incorporate by reference paragraphs 1-64 of this Second Amended Complaint as if fully set forth herein.

66. [redacted]

67. [redacted]

68. [redacted]

69. [redacted]

70. [redacted]

[redacted] two other members of the Arrow Group were defendants in patent infringement litigation on the '314 patent in this Court, based on their submission of Abbreviated New Drug Application ("ANDA") No. 79-167 for a rosuvastatin calcium drug product. Those Arrow Group members were Cobalt Pharmaceuticals, Inc. ("Cobalt Canada") and Cobalt Laboratories, Inc. ("Cobalt U.S."), and the litigation was *AstraZeneca Pharms. LP et al. v. Cobalt Pharms. Inc. and Cobalt Labs. Inc.*, Civ. A. No. 07-811-JJF-LPS.

71. [redacted].

72. [redacted].

73. [redacted].

74. [redacted].

75. [redacted]

[redacted]

76. [redacted]

77. [redacted]

78. [redacted]

[redacted]. On information and belief, on June 16, 2009, Watson Pharmaceuticals entered into an agreement with the head of the Arrow Group, Robin Hood Holdings Limited ("Robin Hood"), to acquire the Arrow Group.

79. [redacted]

80. [redacted]

[redacted]

81. [redacted]

82. [redacted]

83. [redacted].

84. [redacted].

85. [redacted].

86. On information and belief, on December 2, 2009, Watson Pharmaceuticals completed the acquisition of the Arrow Group; after the acquisition, Cobalt Canada and Cobalt U.S. joined Watson Labs (NV) as wholly-owned subsidiaries of Watson Pharmaceuticals. On information and belief, through the acquisition of the Arrow Group, Watson Pharmaceuticals acquired and succeeded to the Cobalt companies' rights in ANDA No. 79-167 for rosuvastatin calcium drug products, and on [redacted].

87. [redacted].

88. [redacted]

89. On information and belief, on February 26, 2010, EGIS filed DMF No. 23592 with the FDA for rosuvastatin [redacted].

90. On information and belief, [redacted] Watson Labs (NV) filed NDA No. 202172 with the FDA seeking approval for rosuvastatin zinc drug products, i.e., the Watson Rosuvastatin Tablets. [redacted].

91. [redacted]. On October 26, 2010, the original complaint was filed against Watson Labs (NV) for infringement of the '314 patent (D.I. 1), and on May 9, 2011, the Court permitted amendment of the Complaint to add charges of infringement of the '618 and '152 patents. On

information and belief, EGIS learned of these pleadings on or about the dates the original Complaint was filed and the Court permitted amendment of the Complaint, respectively.

92. [redacted].

93. On information and belief, if the FDA approves NDA No. 202172 [redacted] Watson Labs (NV) in the United States before the expiration of the '314 patent will cause infringement of one or more claims of the '314 patent.

94. On information and belief, the Watson Rosuvastatin Tablets, if approved by the FDA, will be [redacted] marketed, offered for sale, and sold in the United States by Watson Labs (NV), which will constitute direct infringement of the '314 patent by Watson Labs (NV). On information and belief [redacted] marketing, offering for sale, and sale will occur with EGIS's specific intent and encouragement, and will be conduct that EGIS knows or should know will occur. On information and belief, EGIS will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of the '314 Patent Plaintiffs' rights under the '314 patent.

95. Under 35 U.S.C. § 271(b), if the FDA approves NDA No. 202172, [redacted] for Watson Labs (NV) [redacted] market, offer for sale, and sell in the United States before the expiration of

the '314 patent will induce infringement by Watson Labs (NV) of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

96. On information and belief, EGIS has knowledge of the '314 patent and will knowingly induce infringement of the '314 patent, if the FDA approves NDA No. 202172 before the expiration of the '314 patent. On information and belief, if the FDA approves NDA No. 202172, EGIS [redacted] despite an objectively high likelihood that Watson Labs (NV)'s [redacted] marketing, offering for sale, and sale of those Tablets in the United States will constitute infringement of a valid patent. On information and belief, this risk is either known to EGIS, or is so obvious that it should be known to EGIS.

97. The '314 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '314 Patent Plaintiffs have no adequate remedy at law.

COUNT V

Inducement of Infringement of United States Patent No. 6,858,618 Under 35 U.S.C. § 271(b) by EGIS

98. The '618 Patent Plaintiffs incorporate by reference paragraphs 1-97 of this Second Amended Complaint as if fully set forth herein.

99. [redacted] Watson Labs (NV) [redacted] market, offer for sale, and sell in the United States before the expiration of the '618 patent through Watson Pharmaceuticals' Global Generic segment.

100. On information and belief, if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV)'s sale of the Watson Rosuvastatin Tablets in the United States with their associated labeling before the expiration of the '618 patent, will cause infringement of one or more claims of the '618 patent.

101. On information and belief, the Watson Rosuvastatin Tablets, if approved by the FDA, will be [redacted] sold in the United States by Watson Labs (NV), and will be prescribed and administered to human patients to treat HeFH, which uses will constitute direct infringement of the '618 patent. On information and belief, these uses will occur with EGIS's specific intent and encouragement, and will be uses that EGIS knows or should know will occur. On information and belief, EGIS will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of the '618 Patent Plaintiffs' rights under the '618 patent.

102. Under 35 U.S.C. §271(b), if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV) [redacted] sell in the United States, [redacted] Watson Labs (NV)'s sale of those Tablets in the United States before the expiration of the '618 patent, which claims a use of those Tablets, will induce infringement of one or more claims of the '618 patent, either literally or under the doctrine of equivalents.

103. The '618 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '618 Patent Plaintiffs have no adequate remedy at law.

COUNT VI

Inducement of Infringement of United States Patent No. 7,030,152 Under 35 U.S.C. § 271(b) by EGIS

104. The '152 Patent Plaintiffs incorporate by reference paragraphs 1-103 of this Second Amended Complaint as if fully set forth herein.

105. On information and belief, if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV) [redacted] market, offer for sale, and sell in the United States before the expiration of the '152 patent through Watson Pharmaceuticals' Global Generic segment.

106. On information and belief, if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV)'s sale of the Rosuvastatin Tablets in the United States with their associated labeling before the expiration of the '152 patent, will cause infringement of one or more claims of the '152 patent.

107. On information and belief, the Watson Rosuvastatin Tablets, if approved by the FDA, will [redacted] sold in the United States by Watson Labs (NV), and will be prescribed and administered to human patients for the primary prevention of cardiovascular disease, which uses will constitute direct infringement of the '152 patent. On information and belief, these uses will occur with EGIS's specific intent and encouragement, and will be uses that EGIS knows or should know will occur. On information and belief, EGIS will actively induce, encourage, aid, and abet this prescription and administration, with knowledge

and specific intent that these uses will be in contravention of the '152 Patent Plaintiffs' rights under the '152 patent.

108. Under 35 U.S.C. § 271(b), if the FDA approves NDA No. 202172, [redacted] and sell in the United States, [redacted] Watson Labs (NV)'s sale of those Tablets in the United States before the expiration of the '152 patent, which claims a use of those Tablets, will induce infringement of one or more claims of the '152 patent, either literally or under the doctrine of equivalents.

109. The '618 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '152 Patent Plaintiffs have no adequate remedy at law.

COUNT VII
Declaratory Judgment of Inducement of Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(b) by EGIS

110. The '314 Patent Plaintiffs incorporate by reference paragraphs 1-109 of this Second Amended Complaint, and in particular Count IV, as if fully set forth herein.

111. [redacted] Watson Labs (NV) [redacted] market, offer for sale, and sell in, the United States. On information and belief, Watson Labs (NV) has made substantial preparations [redacted] market, offer for sale, and sell those Tablets in, the United States.

112. [redacted] Watson Labs (NV) intends to commence [redacted], marketing, offering for

sale, and sale, of the Watson Rosuvastatin Tablets immediately upon approval of NDA No. 202172 by the FDA.

113. Under 35 U.S.C. § 271(b), if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV) [redacted] market, offer for sale, and sell in the United States before the expiration of the '314 patent will induce infringement by Watson Labs (NV) of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

114. The '314 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '314 Patent Plaintiffs have no adequate remedy at law.

115. An actual controversy exists relating to EGIS's threatened inducement of infringement of the '314 patent.

COUNT VIII

Declaratory Judgment of Inducement of Infringement of United States Patent No. 6,858,618 Under 35 U.S.C. § 271(b) by EGIS

116. The '618 Patent Plaintiffs incorporate by reference paragraphs 1-115, and in particular Count V, of this Second Amended Complaint as if fully set forth herein.

117. [redacted] Watson Labs (NV) [redacted] market, offer for sale, and sell in, the United States. On information and belief, Watson Labs (NV) has made substantial preparations [redacted] market, offer for sale, and sell those Tablets in, the United States.

118. [redacted] Watson Labs (NV) intends to commence [redacted] marketing, offering for sale, and sale, of the Watson Rosuvastatin Tablets immediately upon approval of NDA No. 202172 by the FDA.

119. Under 35 U.S.C. §271(b), if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV) [redacted] sell in the United States, [redacted] Watson Labs (NV)'s sale of those Tablets in the United States before the expiration of the '618 patent, which claims a use of those Tablets, will induce infringement of one or more claims of the '618 patent, either literally or under the doctrine of equivalents.

120. The '618 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '618 Patent Plaintiffs have no adequate remedy at law.

121. An actual controversy exists relating to EGIS's threatened inducement of infringement of the '618 patent.

COUNT IX

Declaratory Judgment of Inducement of Infringement of United States Patent No. 7,030,152 Under 35 U.S.C. § 271(b) by EGIS

122. The '152 Patent Plaintiffs incorporate by reference paragraphs 1-121, and in particular Count VI, of this Second Amended Complaint as if fully set forth herein.

123. [redacted] Watson Labs (NV) [redacted] market, offer for sale, and sell in, the United States. On information and belief, Watson Labs (NV) has made substantial

preparations [redacted] market, offer for sale, and sell those Tablets in, the United States.

124. On information and belief, [redacted] Watson Labs (NV) intends to commence [redacted] marketing, offering for sale, and sale, of the Watson Rosuvastatin Tablets immediately upon approval of NDA No. 202172 by the FDA.

125. Under 35 U.S.C. §271(b), if the FDA approves NDA No. 202172, [redacted] sell in the United States, [redacted] Watson Labs (NV)'s sale of those Tablets in the United States before the expiration of the '152 patent, which claims a use of those Tablets, will induce infringement of one or more claims of the '152 patent, either literally or under the doctrine of equivalents.

126. The '152 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '152 Patent Plaintiffs have no adequate remedy at law.

127. An actual controversy exists relating to EGIS's threatened inducement of infringement of the '152 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

(1) holding that the claims of the '314, '618, and '152 patents are valid and enforceable;

(2) holding that the submission of NDA No. 202172 by Watson Labs (NV) to the FDA infringes one or more claims of each of the '314, '618, and '152 patents under 35 U.S.C. § 271(e)(2)(A);

(3) holding that EGIS will induce infringement of one or more claims of each of the '314, '618, and '152 patents under 35 U.S.C. § 271(b);

(4) declaring that, under 35 U.S.C. § 271(b), if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV) [redacted] market, offer for sale, and sell in the United States before the expiration of the '314 patent will induce infringement of one or more claims of the '314 patent.

(5) declaring that, under 35 U.S.C. §271(b), if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV) [redacted] sell in the United States, [redacted] Watson Labs (NV)'s sale of those Tablets in the United States before the expiration of the '618 patent, will induce infringement of one or more claims of the '618 patent.

(6) declaring that, under 35 U.S.C. §271(b), if the FDA approves NDA No. 202172, [redacted] Watson Labs (NV) [redacted] sell in the United States, [redacted] Watson Labs (NV)'s sale of those Tablets in the United States before the expiration of the '152 patent, will induce infringement of one or more claims of the '152 patent.

(7) ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Watson Rosuvastatin Tablets shall be no earlier than the expiration date of the last to expire of the '314, '618, and '152 patents and any additional periods of exclusivity;

(8) enjoining Watson Labs (NV), Watson Pharmaceuticals, and Watson Pharma, and all persons acting in concert with any of them, from commercially manufacturing, using, offering for sale, or selling the Watson Rosuvastatin Tablets within the United States or importing into the United States the Watson Rosuvastatin Tablets prior to the expiration of the last to expire of the '314, '618, and '152 patents and any additional periods of exclusivity;

(9) enjoining EGIS, and all persons acting in concert with EGIS, [redacted] API that is the subject of DMF No. 23592, prior to the expiration of the last to expire of the '314, '618, and '152 patents and any additional periods of exclusivity;

(10) declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;

(11) awarding Plaintiffs their costs and expenses in this action; and

(12) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

Respectfully submitted,

/s/ Mary W. Bourke

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Dated: November 23, 2011
Redacted Version: November 23, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on the 23rd day of November, 2011, I electronically filed a true and correct copy of **SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT** (Redacted Version) and served the below individuals by electronic mail:

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